Remarks/Argument:

Description of Amendments to the Claims.

Applicants respectfully request entry of this amendment after final rejection. The amendment is believed to put the case in condition for allowance and overcomes the new basis for rejection.

Claims 10 and 17 have been cancelled in this amendment. Accordingly, all rejections to such claims are obviated. Claims 7, 8, and 16, are currently being prosecuted.

Claim 7 has been amended to state that the claimed method disrupts eukaryotic cells. Support for this amendment is found throughout the specification in its explicit and implied references to assaying cells extracted from lymph node intra-operatively. Such techniques are known to be used to assay eukaryotic cells such as white blood cells from the patient. Support is also found, for example, in paragraph [0025] of the published specification where the described assay is for porcine b-actin, a gene of eukaryotic origin.

Claim 7 has also been amended so that the method is conducted with a disruption element of about 6mm and which is only slightly smaller than the container in which it is placed. Support for this amendment is found at paragraphs [0009] and [0012] of the published application. The amendment to the claim reciting mechanically imparted rolling contact which is not induced by sonication or vibration is supported by paragraphs [0004] and [0007] of the published application.

Accordingly, no new matter has been added.

Response to Rejections

The claims are subject to obviousness rejections over Murphy('522) in view of Spelsberg ('846) and Gautsch ('501) and further in view of Hoon ('105) in the case of claim 16. These rejections are respectfully traversed for the following reasons.

The rejections are based on the following combination:

1. Lysing/disrupting cells in a container with disruption elements which are beads and removing DNA or RNA for a time of one minute or less (Murphy),

2. Conducting a disruption process in a matter of seconds (Gautsch),

3. Conducting the process in the presence of stabilizing solution (Spelsberg, Gautsch),

4. Conducting the process using lymph cell tissue in the case of claim 17 (Gautsch),

5. Conducting the process for use in an intraoperative procedure in the case of claim 17 (Hoon).

Applicants continue to assert their position that the combination of references suggested by the Examiner is improper for the reasons set forth in the last response. Additionally, they note the Murphy reference cannot be combined with any of them. It is directed entirely to a method that employs a sonication procedure. An ultrasound bath is exemplary of such a method. Very small beads (less than 1 mm) are used in a bath. Vibration is induced into the beads by the waves pulsed into the bath. Col. 5, lines 50-54 and Col. 7, lines 55-65. This, by itself, renders it non-analagous and certainly incapable of combination with the other cited references.

Further, the method is directed entirely to solving the problem of breaking open tough bacterial cells. Col. 1, lines 46-55. In so doing, it notes that the prior art methods of grinding or shaking samples is undesirable further making combination with the other cited references inappropriate.

The Murphy reference is also said to describe a rapid process and one that can be applied in less than one minute. This, however, cannot be found anywhere in the patent. Indeed, Table 1 indicates that process times of 10 minutes are more typical.

Applicants also note that while Spelsberg does describe a tissue solution it does not describe, refer to, or suggest the use of stabilizing solutions. No information is given regarding the composition of a stabilizing solution. Perhaps a solution is used for lubrication or wetting the tissue but there is no way to know since it is not described. Likewise, it cannot be inferred from anything in the reference that the solution is a stabilizing solution.

Even if one were to combine the references, they would not render the instant invention obvious. The claimed invention is directed to the rapid mechanical disruption of cells and tissue without resort to sonication or vibration in which the disruption is induced by rolling contact of particularly dimensioned components that are not difficult to obtain. The method can thus be practiced simply and the devices for practicing the method can be simply made and used.

Murphy shows the use of a sonication-based system which is much more complex and does not suggest an ability to perform the method in anywhere near the time frame of the instant invention. Spelsberg shows a mechanical device but it is more complicated than the instantly claimed invention in that it requires a machined component and only operates in a continuous fashion. It also does not use the more efficient rolling contact to cause the disruption as is the case in the instant invention. Gautsh shows an oscilliatory method which is inapposite to that of Murphy and Spelsberg. It is a much more complicated method in that it requires a sophisticated, motorized device that is finely made and balanced to practice it. Hoon describes the desirability of conducting intra-operative assays but provides no insight into doing so with the instantly claimed process.

Nothing in any of the references combined or separate, suggest a simple and rapid method that operates in the manner claimed in this invention. Accordingly, the rejections are believed to be overcome and a notice of allowance is respectfully solicited.

Respectfully submitted,

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